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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/470,667	12/22/1999	AKIRA ASAKURA	13735(109700	6424

7590 06/04/2002  
Mark E. Waddell, Esq.  
Bryan Cave LLP  
245 Park Avenue  
New York, NY 10167-0034

EXAMINER

WALICKA, MALGORZATA A

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 06/04/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/470,667

Applicant(s)

ASAKURA ET AL.

Examiner

Malgorzata A. Walicka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 1-3,9 and 17-28 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6,7 and 32 is/are allowed.
- 6) ☒ Claim(s) 4,5,8,10,11,29-31,33 and 34 is/are rejected.
- 7) ☒ Claim(s) 12-16 and 36 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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Response to Office Action including Amendment and Petition for Extension of Time, filed on March 12, 2002 as paper No. 15, is acknowledged. Claims 4, 6, 7, 8, 10, 11, and 16 have been amended. New claims 29-36 have been added. Claims 1-36 are pending in the application. Claims 4-8, 10-16 and 29-36 are the subject of this Office Action. Claims 1-3, 9, and 17-28 are withdrawn from consideration as drawn to the non-elected invention.

### **Detailed Office Action**

#### *1. Rejections withdrawal*

In the light of amendments to claims 4, 6, 7, 10, 11, and 16, as well as in the light of Applicants's arguments, rejections of claims 4-7 and 10-16 under 35 USC section 112, first paragraph, made in the previous Office Action, Paper No. 13, has been withdrawn.

#### *2. New rejection*

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

*Wd* Claim 4 and 5 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In the absence of the hand of man, naturally occurring proteins and/or nucleic acids are considered non-statutory subject matter; *Diamond v. Chakrabaty*, 206 USPQ 193 (1980). This rejection may be overcome by

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amending the claims to contain wording such as "An isolated nucleic acid". It should be noted that a recombinant enzymes/proteins are assumed to be identical to those produced naturally unless otherwise indicated.

Claim 10 and 11 are rejected under 35 U.S.C. § 101 because the claimed invention is directed toward non-statutory subject matter. These claims include humans within their scope. This rejection may be overcome by amending the claims to contain wording such as "A host cell transformed ...".

wk Claims 10-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for host cells transformed or transfected with the claimed plasmids, does not reasonably provide enablement for all possible host organisms similarly transformed or transfected. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claim encompasses all multicellular organisms transformed or transfected with specific plasmids. The specification, however, only describes the transfection of host cells. Despite knowledge in the art of transformation techniques and the production of transgenic organisms, the specification fails to provide guidance regarding what organisms would be expected to tolerate expression of the heterologous enzymes encoded by the claimed plasmids. It remains a priori unpredictable as to the result of systemic expression of the several heterologous enzymes during growth and development of complex multicellular organisms. The use of regulated promoters is insufficient because of the fact that they remain "leaky" and allow low levels of

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expression. In the absence of information regarding the effects of systemic expression of the disclosed proteins in complex multicellular organisms, it is unpredictable as to what transgenic multicellular organisms can be produced with DNAs encoding these proteins. Lastly, while recombinant techniques are available, it is not routine in the art to attempt large numbers of transgenic complex multicellular organisms, where the expectation of successful transformation/transfection is unpredictable based on the instant disclosure. Therefore, one of ordinary skill would require guidance, in order to make and use host organisms in a manner reasonably commensurate with the scope of the claim. Without such guidance, the experimentation left to those skilled in the art is undue.

### 3. Rejections necessitated by amendments

#### 3.1. 35 U.S.C., section 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

*delete for insertion*  
New claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The language of the claim is confusing as to whether the fragment of SEQ ID NO:5 has AADH activity. It is suggested that the claim be amended to recite "An isolated polynucleotide comprising a sequence encoding a fragment of SEQ ID NO:5 of at least 95 amino acid residues, which fragment..." The examiner assumes for purposes of further examination that Applicants' invention is

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directed to an isolated polynucleotide which encodes a fragment of SEQ ID NO:5 of at least 95 amino acid residues which fragment has an alcohol and aldehyde dehydrogenase activity (AADH). New claim 34 is included in this rejection as depending on claim 30.

New claim 35 is rejected as being identical to originally filed claim 12.

### 3.2. *Lack of written description*

*g/l, — n dr*  
*Develop* Amended claim 8 and the newly added claim 33 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not disclose a repeatable process to obtain the vector pSSA102R. The arguments presented by Applicants on page 13 of the Response, paper No. 15, are not found persuasive, because the quoted process to obtain the vector is unclear. In particular, it is unclear from the specification how one of ordinary skill in the art would obtain the specific insert that was used. Applicants specification teaches only a portion of the sequence of this insert, therefore the process of obtaining it is unclear. Accordingly, it is deemed that a deposit of this vector should have been made in accordance with 37 CFR 1.801-1.809 as requested in the previous Office Action, paper No. 13.

*g/l, — n dr* New claim 29 is rejected as directed to a large and variable genus of DNA molecules encoding polypeptides that are at least 80% identical to SEQ ID NO:5. However, the disclosure does not set forth DNA molecules encoding polypeptides having sequences that are at least 80% identical to SEQ ID NO:5. The specification teaches only one representative of the claimed genus of DNA molecules that is SEQ ID

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NO:1 encoding SEQ ID NO:5 having AADH activity. No information, beyond the characterization of SEQ ID NO:5 and SEQ ID NO:1, has been provided by Applicants, which would indicate that they had possession of the claimed genus of DNAs. Neither the claim nor the specification contain any disclosure of the function of all the polypeptide sequences that are at least 80% identical to SEQ ID NO:5. The genus of claimed DNA molecules is a large variable genus and its species encode polypeptides which can have a wide variety of functions. Therefore, DNA molecules encoding many functionally unrelated polypeptides are encompassed within the scope of the claim. The specification does not provide information sufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that Applicants had possession of claimed invention at the time the instant application was filled.

*what*  
*and*  
*genus* New claim 31 is directed to a large genus of DNA molecules which encode a fragment comprising at least 44 [should be 45, M.W.] amino acid residues of a polypeptide having at least 80% identity to SEQ ID NO:5, wherein said polypeptide has AADH activity. The disclosure does not set forth DNA molecules encoding polypeptides having sequences that are at least 80% identical to SEQ ID NO:5. The specification teaches only one representative of the claimed genus of DNA molecules that is SEQ ID NO:1 that encodes SEQ ID NO:5, the fragment of which, comprising amino acids 136-180 has the desired activity. No information, beyond the characterization of SEQ ID NO:5 has been provided by Applicants, which would indicate that they had possession of the claimed genus of DNAs. Neither the claim nor the specification contain any

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disclosure of the structure of a polypeptide sequence that is at least 80% identical to SEQ ID NO:5 and contains a 45 amino acid fragment that has AADH activity. Therefore, one skilled in the art cannot reasonably conclude that Applicants had possession of claimed invention at the time the instant application was filled.

*W.D.* New claim 34 is included in this rejection as depending on claim 29 or 30, or 31.

### 3.3. *Scope of enablement*

New claims 29 and 31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the DNA molecule of SEQ ID NO:1, or DNA encoding SEQ ID NO:5, that contain a 45 amino acid fragment having alcohol and aldehyde dehydrogenase activity, does not reasonably provide enablement for DNA encoding polypeptides having at least 80% identity to SEQ ID NO:5 or polynucleotides which encode a fragment of at least 45 amino acid residues of polypeptides having at least 80% identity to SEQ ID NO:5. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are so broad as to encompass any DNA, from any natural and man made source, wherein said DNA encodes the amino acid sequence that is at least 80% identical to SEQ ID:5, or the DNA molecule comprising a fragment encoding a sequence of 45 amino acids, wherein said fragment originates from a polypeptide that is at least 80% identical to SEQ ID NO:5.



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The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of DNA molecules broadly encompassed by the claims. The specification provides for SEQ ID NO:1 encoding the AADH of SEQ ID NO:5 and a 45 amino acid residue fragment of SEQ ID NO:5, said fragment having the AADH activity. Since a single change in amino acid sequence may turn the protein inactive, the claimed invention encompasses many DNA molecules that do not encode for the AADH activity.

While hybridization, expression and sequencing of encoded protein and measuring its enzymatic activity is well known in the art, and the skills of artisans highly developed, it is not a routine in the art to screen all DNA libraries, from natural and man-made sources, express selected DNA molecules, isolate the proteins, measure their activity and select the one having at least 80% identity to SEQ ID NO:5 and the AADH activity. It is not a routine to further examine 45 amino acid fragments of such polypeptides for selecting those that retain the AADH activity. The specification does not support the broad scope of the claims that encompass extremely large number of DNAs. Applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including DNA comprising variants of SEQ ID NO:1 that encode the amino acid sequence that is at least 80% identical to SEQ ID NO:5 and/or containing a 45 amino acid fragment that possesses the AADH activity.

The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance,

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determination which of DNAs will encode a polypeptide retaining the AADH activity is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

#### **4. Conclusion**

Claims 6, 7 and 32 are allowed for reasons indicated in the previous Office Action, paper no. 13.

Claim 12-16 and 36 are objected to as being dependent upon a rejected base claim 10, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

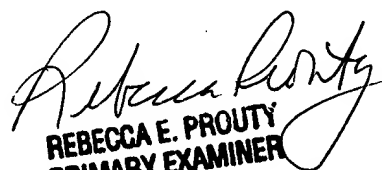
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (703) 305-7270. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (703) 308-3804. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 308-0196.

Malgorzata A. Walicka, Ph.D.

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REBECCA E. PROUTY  
PRIMARY EXAMINER  
GROUP 1600  
1600